

FDA Food Safety Modernization Act One-Year Progress Report

Since President Obama signed the Food Safety Modernization Act (FSMA) on January 4, 2011, the Food and Drug Administration (FDA) has made significant progress in developing proposed rules to implement the sweeping food safety reform law, publishing mandated reports, and taking important steps toward increasing overall food safety capacity in the United States. Below are brief summaries of what FDA has accomplished to date.

Highlights

- Issued interim final rules on criteria for administrative detention and used this authority three times; issued interim final rules on prior notice of imported food.
- Issued guidance to the seafood industry on food safety hazards and to the dietary supplement industry regarding new dietary ingredients.
- Conducted extensive domestic and foreign outreach to all stakeholders to receive input in developing the proposed preventive control rules.
- Established the Produce Safety Alliance and the Food Safety Preventive Controls Alliance.
- Met the FSMA mandate for foreign food safety inspections, and is well on its way to meeting the 5-year inspection frequency mandate for high-risk domestic food facilities.
- Continued to build State-Federal and global partnerships.

Initial Steps in FSMA Implementation Completed

During the first year of FSMA, FDA has completed a number initial implementation steps, including:

- Consumer-Friendly Web Search for Recalls. FDA launched a more consumer-friendly recall search engine on the FDA website.
- Guidance to Seafood Industry on Food Safety Hazards. FDA issued its updated guide to the seafood industry on hazards associated with fish and fishery products and appropriate controls for those hazards.
- Administrative Detention of Foods. Allows FDA to administratively detain food products that it has reason to believe are adulterated or misbranded for up to 30 days, if needed. FDA has begun using this authority.
- Prior Notice of Imported Food. FDA issued an interim final rule that requires a person submitting prior notice of imported food, including food for animals, to report the name of any country to which the article has been refused entry.

- Joint Anti-Smuggling Strategy. FDA and the Department of Homeland Security issued a joint anti-smuggling strategy to help to identify and prevent smuggled foods from entering the U.S. and posing a threat to national security and consumer safety.
- Fee Schedule. FDA announced the fiscal year 2012 fee schedule for certain domestic and foreign facility reinspections and for failure to comply with recall orders.
- Authority to Suspend the Registration of Food Facilities. FDA has the authority to suspend the registration of food facilities to prevent the import and export into the U.S. in certain circumstances involving food that has a reasonable probability of causing serious adverse health consequences or death to humans or animals.
- Product Tracing Pilots Launched. FDA announced that the Institute of Food Technologists (IFT) will carry out two new pilot projects aimed at enhancing the agency's and industry's ability to trace products responsible for foodborne illness outbreaks.

Inspections

FDA has met the FSMA mandate for foreign inspections. For domestic inspections, the FSMA mandate is based on a 5-year time period. In the past year, FDA has defined its high risk and non high risk domestic food facility inventories and in FY11, FDA and its State partners conducted more than 20,000 food facility inspections. At this rate the Agency will most assuredly meet the domestic food inspection frequency mandates defined in FSMA. In addition, FDA is developing new risk-based approaches to domestic inspection to maximize public health benefit.

Outreach and Technical Assistance

Communication and outreach have played an essential role as FDA implements the various FSMA provisions.

- FDA has participated in more than 350 meetings with industry leaders, farmers, consumers, public officials, and academics.
- On produce safety, FDA has worked very closely with USDA, which has an established relationship with farmers, and taken part in 14 farm tours across the country to gather input on how the proposed rules can work feasibly across the diversity of commodities and growing conditions and practices.
- FDA, the US Department of Agriculture, and the National Institute of Food and Agriculture entered into an agreement to collaborate on the establishment of a competitive grant program for food safety training and other projects.
- FDA held three public meetings on preventive controls, import provisions, and changes to inspection and compliance programs in a preventive controls environment.
- FDA has participated in more than 70 meetings globally to discuss the international impact of FSMA. This includes trips by the Deputy Commissioner for Foods to China, Mexico, Canada and the European Union.

- FDA participated in, and helped fund, the establishment of the Produce Safety Alliance and the Food Safety Preventive Controls Alliance to help industry, especially small and very small firms, to comply with the requirements.
- FDA provided information to the business community through the extension services of 49 land-grant colleges and universities.
- FDA established a FSMA webpage that now has more than 10,000 subscribers, includes more than 100 Frequently Asked Questions by topic, and features videos, webinars, presentations, and print materials.

FSMA Reports to Congress

FDA submitted to Congress the first annual "Report on Food Facilities, Food Imports, and FDA Foreign Offices" and the "Biennial Report to Congress on the Food Emergency Response Network (FERN)."